

was reached. Statements made by the undersigned during the interview are included herein.

The Office Action indicates that claims 20-24 are withdrawn from further consideration as being drawn to a nonelected species. However, in making the election, Applicants had indicated that claims 20-22 should be examined pursuant to the election, and Applicants respectfully request that these claims be included herein.

The previous requirement for restriction included a requirement for election of species. Applicants provisionally elected claims to methods of treating bacterial infections diseases, solely for the purpose of commencing examination. Claim 20 calls for the treatment of pneumonia, a bacterial infection, in an HIV-positive patient. Claim 21 calls for treatment of chronic infections and should be examined, at least to the extent that it reads on bacterial infections. Claim 22 is dependent on claim 21 and refers to specific infections, some of which are bacterial. It, too, should be examined, at least to the extent that it reads on the provisionally elected invention.

Applicants thus request that claims 20-22 be included in the provisionally elected claims under examination.

Claims 1-19, 25-44 and 61-63 stand rejected as obvious over Johnson et al., WO 98.50399. The reference is asserted as disclosing cyclic AGPs.

"Cyclic AGP", as called for in claims 61-63, is defined in the specification (p. 3 lines 7-9) as "an azacycloalkyl or (azacycloalkyl)alkyl glucosaminide phosphate, wherein a 2-deoxy-2-amino-b-D-glucopyranose (glucosamine) is glycosidically linked to an azacycloalkyl or (azacycloalkyl)alkyl (aglycon) group". All the claim-designated compounds herein must have an azacycloalkyl or azacycloalkyl(alkyl) grouping. There is, however, no disclosure of any such compounds in Johnson et al. In those compounds the aglycon unit is a linear moiety. The examiner notes that Johnson et al do not provide an explicit example of a cyclic AGP. However, Johnson et al. provide no disclosure, explicit or implicit, of any cyclic AGP compounds, as this term is defined herein, nor do Johnson et. al disclose, implicitly or explicitly, any compounds having the cyclic moiety in the aglycon portion of the compounds defined in claim 1.

Similarly, the examiner asserts that Example 3 of Johnson provides motivation to use various types of cyclic AGPs to treat bacterial infections. However Johnson et al. cannot provide any incentive to use such compounds, as they are not disclosed in that reference, nor were they known in the art. In fact, three of the four Applicants have recently obtained a patent with claims to some of these compounds, U.S. patent 6,525,028. It cannot be obvious to use compounds that were not known, for any purpose. Applicants respectfully request withdrawal of the rejection for obviousness.

Claims 1-19, 25-44 and 61-63 stand rejected under the first paragraph of Section 112. The rejection is initially written as a rejection for lack of a written description of the claimed invention in the specification of this application. Subsequent language appears to indicate that a rejection for lack of enabling disclosure is meant (or perhaps a rejection on both grounds is meant).

To the extent that the rejection is based on lack of a written description, Applicants note that the specification uses the same language as the claims. The specification does therefore comply with the written description requirement since it is made abundantly clear to those reviewing the application that the inventors had possession of the claimed concepts. Should the Examiner maintain this rejection, a more detailed statement of why the Application does not contain a written description of the claimed invention is respectfully requested.

To the extent that the rejection is based on lack of enabling disclosure for the claims, Applicants first note that the specification does in fact contain examples of the treatment of subjects to prevent a subsequent bacterial infection, in Examples 4 and 5.

In Example 4, three of the claim-designated compounds were administered to test subjects (mice) in advance of their being challenged with a bacterial culture (*Lysteria monocytogenes*). The three compounds (shown in examples 1, 2 and 3) were of formula (I) in which the acyl groups R₁-R₃ were, respectively, tetradecanoyl (C₁₄), dodecanoyl (C₁₂) and decanoyl (C₁₀). In Example 5, the same three compounds were administered to test animals in advance of their being contacted with influenza. In both examples, prophylactic, i.e. preventative, effects were demonstrated. Applicants submit that the

three test compounds are well representative of the claim-designated compounds in general, and even more so of those designated in dependent claims 2-14, 27-39 and 62-63.

The examiner also has indicated that the test data is insufficient to enable those of ordinary skill in the art to practice the invention. Applicants, however, disagree.

As stated in the specification, the claim-designated compounds are members of a much larger group of compounds known to be pharmaceutically active, namely compounds that share certain structural similarities with mono-phosphoryl lipid A compounds. The present compounds have sufficiently different structures from monophosphoryl lipid A-type compounds (or, as discussed below, from acyclic aminoalkyl glucosaminide phosphates) so as to not be obvious therefrom. However, the claim-designated compounds also share sufficient structural similarity with both types of compounds such that once it has been established that the cyclic AGPs have antibacterial activity, i.e., by tests such as those described in Examples 4 and 5, those skilled in the art would expect the compounds to exhibit generally similar activity to the known compounds (i.e., monophosphoryl lipid A-type compounds and acyclic AGPs).

Applicants note that the same test for influenza as in Example 5 was carried out with monophosphoryl lipid A (WO 01/90129, submitted in the accompanying Information Disclosure Statement, p. 26, Example 2) and with acyclic AGPs (*Id.*, p. 27, Example 4). Applicants thus submit that, from this information, once those skilled in the art would be aware of the cyclic AGPs of this application, they would expect these compounds to possess similar activity to that disclosed for monophosphoryl lipid A and the acyclic AGPs disclosed in WO 01/90129. In addition, those skilled in the art would expect that such activity, including activity against other bacteria, and appropriate dosages, could readily be confirmed by the use of no more than routine experimentation using commonly employed assays.

Should the Examiner hold a different opinion, detailed reasoning supporting such a position is respectfully requested.

CONCLUSION

In view of the foregoing, Applicants submit that all claims under examination are allowable, and request examination of the full scope of the generic claims.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned.

Respectfully submitted,

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